

Shimizu and further in view of Tonge et al. Claims 12 and 14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shimizu and further in view of Geistlich et al. Claims 5-17 and 19-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shimizu and further in view of Stensaas et al. Insofar as these rejections could apply to the claims, as amended, they are respectfully traversed.

Independent claim 1 has been amended to define a nerve regeneration tube formed of a single sheet of a resorbable sidewall material consisting essentially of collagen sheet material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, the sheet material further having a fibrous inner surface opposite the smooth barrier surface. Method claim 15 also has been amended to include all of these features.

The Shimizu reference discloses a tube with a sidewall having three layers, a central biodegradable layer 11 or 21, having an outer coating layer 13 or 23 and an inner coating layer 12 or 22. Although the outer and inner layers may be collagen, the central biodegradable tube layer is described at column 3, second full paragraph, as being a "mesh material made of a material selected from the group consisting of polyglycolic acid, polylactic acid (L or DL), copolymer of glycolic acid and lactic acid, copolymer of lactic acid and ε-caprolactone, polydioxanone and copolymer of glycolic acid and trimethylene carbonate, which is able to maintain its shape in the body for a certain period of time despite being biodegradable".

The Shimizu reference thus requires a non-collagen central tube layer with inner and outer coating layers of gelatin or collagen.

The Shimizu reference fails to teach or even remotely suggest a tube formed of a single sheet of a resorbable sidewall material consisting essentially of collagen sheet material as defined above.

Under applicable case law, the phrase terminology “consisting essentially of” excludes ingredients and steps that materially affect the basic and novel characteristics of the claimed invention. In view thereof, the Shimizu reference fails to teach or suggest a tube formed of a single sheet of a resorbable sidewall material consisting essentially of collagen sheet material as specifically defined above.

The Shimizu reference also fails to teach or suggest a nerve regeneration tube as defined by amended claim 13. As noted above, the Shimizu reference requires a three-layered structure with a non-collagen central tube layer having inner and outer coating layers of gelatin or collagen. The Shimizu reference fails to teach or suggest a nerve regeneration tube formed of a single sheet of a resorbable sidewall comprising collagen material having a compact, smooth outer barrier surface so as to inhibit solid adhesion thereon and act as a barrier to prevent passage of cells therethrough, the sidewall of the tube further having a fibrous inner surface opposite the smooth barrier surface.

In the absence of any hint whatsoever of a tube formed of single sheet with a compact smooth outer barrier surface and a fibrous inner surface opposite the smooth barrier surface, the Shimizu reference cannot anticipate or render obvious amended claim 13.

With respect to the amended claim 14, Shimizu fails to teach or suggest the tube of claim 13, wherein the collagen material is further required to be derived from peritoneal membrane tissue.

None of the other applied references can be combined with the Shimizu reference to supply the deficiencies thereof.

Tonge et al. teaches a tube filling material, but cannot be combined with Shimizu to suggest a tube formed of a single sheet of resorbable sidewall material as specifically defined above.

The Geistlich et al. patent discloses a collagen material which arguably, without admitting same, could be combined with Shimizu to provide the inner and outer collagen coating layers surrounding the non-collagen central tube 11 or 21 defined in the second full paragraph in column 3 of Shimizu. However, this would not teach or suggest the nerve regeneration tube formed of a single sheet of resorbable sidewall material as specifically defined above.

The Stensaas et al. reference discloses a prosthesis for nerve regeneration which is made of a fluid-impermeable layer composed of silicone, rubber, polyurethane, teflon or nitrocellulose. The Stensaas et al. reference thus cannot be combined with the Shimizu reference to suggest the invention as presently claimed.

In view of the above amendments and remarks, withdrawal of the rejections based on Shimizu, either alone or combined with Tonge et al., Geistlich et al. or Stensaas et al., is respectfully requested.

Applicants submit that the present application is now in condition for allowance. Reconsideration and favorable action are earnestly requested.

Respectfully submitted,



George R. Repper
Attorney for Applicants
Registration No. 31,414
ROTHWELL, FIGG, ERNST & MANBECK, p.c.
1425 K Street, N.W., Suite 800
Washington, D.C. 20004
Telephone: 202-783-6040

Attachments: Marked-Up Copy of Amendments
Request for Extension of Time

Amended Claim: Version with markings to show changes made

1. (Amended) A nerve regeneration tube [with] formed of a single sheet of a resorbable sidewall [comprised] material consisting essentially of collagen sheet material], the sidewall] having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, the [sidewall of the tube] sheet material further having a fibrous inner surface opposite the smooth barrier surface.

2. (Amended) The tube of claim 1, wherein said sidewall [is comprised] material consists essentially of a mixture of Type III and Type I collagen.

3. (Amended) [The tube of claim 2,] A nerve regeneration tube with a resorbable sidewall comprised of collagen material, the sidewall having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, the sidewall of the tube further having a fibrous inner surface opposite the smooth barrier surface, wherein said sidewall is comprised of a mixture of Type III and Type I collagen, and wherein said mixture contains about 1-10% Type III collagen and about 90-99% Type I collagen.

13. (Amended) A nerve regeneration tube [with a] formed of a single sheet of a resorbable sidewall material comprising collagen material [derived from collagen membrane tissue] having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, the sidewall of the tube further having a fibrous inner surface opposite the smooth barrier surface.

14. (Amended) The tube of claim 13, wherein said collagen [membrane tissue is] material is derived from peritoneal membrane tissue.

15. (Amended) A method of producing a nerve regeneration tube as claimed in claim 1, comprising:

a) providing a single sheet of a resorbable sidewall material consisting essentially of collagen sheet material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, and a fibrous surface opposite the smooth barrier surface; and

b) forming said single sheet into a tube having [a] said resorbable sidewall material consisting essentially of said collagen sheet material having [with] said compact, smooth outer barrier surface oriented outwardly, said [sidewall] sheet material having an inner surface comprised of said fibrous surface opposite said smooth barrier surface.

18. (Amended) [The method of claim 17,] A method of producing a nerve regeneration tube as claimed in claim 1, comprising:

a) providing a sheet of collagen material having a compact, smooth outer barrier surface so as to inhibit cell adhesion thereon and act as a barrier to prevent passage of cells therethrough, and a fibrous surface opposite the smooth barrier surface; and

b) forming said sheet into a tube having a sidewall with said compact, smooth outer barrier surface oriented outwardly, said sidewall having an inner surface comprised of said fibrous surface opposite said smooth barrier surface;

wherein said sheet of collagen material has two opposite side edges, and the two side edges of said sheet are brought together to form said tube from said sheet;

further including a step of joining said two side edges together to form said tube from said sheet; wherein the two side edges are joined together by sutures or adhesive.